"EFFECT OF EARLY SUPERVISED REHABILITATION ON MUSCULOSKELETAL TUMOUR SOCIETY RATING SCORE AND KNEE RANGE OF MOTION IN SUBJECTS WITH ENDOPROSTHETIC RECONSTRUCTION OF PROXIMAL TIBIA"- PILOT STUDY

REGISTRATION NO: 271710321

A DISSERTATION SUBMITTED

TO THE TAMIL NADU DR. M.G.R.MEDICAL UNIVERSITY,

CHENNAI,

AS PARTIAL FULFILLMENT OF

THE MASTER OF PHYSIOTHERAPY DEGREE

(ADVANCED PT IN ORTHOPAEDICS)

MAY 2019

CHRISTIAN MEDICAL COLLEGE, VELLORE

TAMIL NADU

2017-2019

BONAFIDE CERTIFICATE

This is to certify that this is a bonafide work of **Mrs. MARIA STEFFY SUMESH KUMAR**, of Christian Medical College and Hospital, Vellore, submitted in partial fulfilment of the requirement for the Masters of Physiotherapy (Advanced PT in Orthopaedics) programme from the Tamil Nadu Dr. M.G.R Medical University, Chennai under the **Registration No. 271710321** for the May 2019 Examination.

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Place: Vellore

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Under the guidance of:

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MASTER OF PHYSIOTHERAPY

From

TAMIL NADU DR. M.G.R MEDICAL UNIVERSITY, CHENNAI

Submitted by

Mrs. Maria Steffy Sumesh Kumar

Registration No: 271710321

May 2019

…… ……

Internal Examiner External Examiner

Dedicated

To

My Family,

My Teachers,

Mentors

Friends,

Well wishers

And the critics

ACKNOWLEDGEMENT

"God is our refuge and strength; an ever-present help in times of trouble."

Psalm 46:1

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MARIA STEFFY

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ABSTRACT

Background:

Proximal tibia is the second most common site for the bone osteosarcoma and giant cell tumor. Several studies confirm the efficacy and success of endoprosthetic replacement as a limb-sparing technique for the treatment of osteosarcoma and other malignant bone tumors. However, the functional status after megaprosthetic reconstruction around the knee is strongly dependent on the competence of the knee extensor mechanism. Although early mobilization and gait training are important factors essential to assure successful rehabilitation, there are no reports on the outcomes following early supervised rehabilitation once the surgery is performed. Therefore in this study we aim to find out if early supervised rehabilitation in patients with Endprosthetic Reconstruction of Proximal Tibia (EPRPT) improves knee joint function and mobility and if there is any change in the outcomes at 3 months follow-up.

Objectives:

- To investigate the effect of early supervised rehabilitation in patients with EPRPT.
- To find out if there is any change in the outcomes at 3 months follow-up.

Design:

Pre test & Post test Experimental Design

Methodology:

Six subjects with a mean age of 26.17 ±10.68 years were included after a written consent. Subjects who have been posted for EPRPT surgery were assessed pre-operatively for Musculoskeletal Tumour Society Score (MSTS), knee range of motion (ROM), limb girth of thigh and calf, tightness at knee, strength of the knee muscle and 6 minute walk test. On the 3rd post op day outcomes were measured. From the 3rd post op day the patient received one session of supervised physiotherapy for 45 minutes including active Mobilization of the Knee, Strengthening of Hip, Knee and Ankle and progressive gait training for 5 days a week up to 1 month. Assessment was done at the end of each week up to 1 month and follow-up assessment at 3 months post surgery. The data obtained was analyzed to find out if outcomes improved with early supervised rehabilitation in patients with endoprosthetic reconstruction of proximal tibia. The follow up data was analysed to find out if there is any change in the outcomes after 3 months post surgery.

Outcome Measures:

Primary Outcome measures

- Knee Range of Motion (ROM).
- Musculoskeletal Tumour Society Score (MSTS).

Secondary Outcome measures

- Hamstring tightness.
- Muscle girth.
- Knee muscle power.
- 6 minute walk test.

Results:

The results showed a significant improvement in the Knee range of motion and the MSTS score following 4 weeks of early supervised rehabilitation (p value <0.05). Despite the early rehabilitation Hamstring tightness was statistically significant at 4 weeks post EPRPT. (p value

<0.05) Knee muscle power improved significantly post EPRPT (p value <0.05). The girth of calf reduced and the girth of thigh did not show much reduction. The 6 min walk distance improved by third month clinically but was not significant statistically.

Conclusion:

Early and supervised physiotherapy post EPRPT significantly improved the MSTS score.The knee range of motion improved significantly with early supervised rehabilitation.The MSTS score and the Knee range of motion were maintained at 3rd month follow-up.

Keywords:

Proximal tibia tumour, knee megaprosthesis, Physiotherapy, MSTS score

1. INTRODUCTION

Bone tumors: Incidence and Types

Although primary bone tumors are rare, certain non-neoplastic conditions, metatstatic disease, and lymphohematologic malignancies may stimulate primary bone tumors. (1) The incidence of benign tumors is higher than a malignant tumor. The most frequently diagnosed histologic subtypes are chondrosarcoma (30% in males and 29% in females), osteosarcoma (16% in males and 17% in females) Ewing's sarcoma (14% in both males and females) and chordoma (8% in males and 5% in females) (2). The age-specific incidence rate shows a bimodal distribution with the first peak at the age of 10-20 years (Osteosarcoma and Ewing's sarcoma) and second peak more than 60 years (primarily chondrosarcoma and to a lesser degree Paget's related osteosarcoma) (1,2). Bone sarcomas are the third most cause for the mortality rate in an adolescent.

Endoprosthetic reconstruction of the proximal tibia

Proximal tibia is the second most common site for the bone osteosarcoma and giant cell tumor. Tibial tumors have a high survival rate than the femoral tumors. Proximal tibia includes 15% of osteosarcoma, 11% of Ewing's sarcoma and 6% of chondrosarcoma.(3) The tibial tumors are a small and posterior extension and involvement of vascular component is rare. (4) With the availability of chemotherapy the survival rates of bone tumors had increased. Initially before 1970's neoadjuvant chemotherapy and amputation are the only treatment option for the bone tumors. After the 1970s with the advancement of technology limb-sparing procedure that is the prosthetic reconstruction are the choice of treatment along with chemotherapy. (3, 6)

There are several techniques available for limb salvage in proximal tibial tumors which includes osteoarticular allograft or allograft-prosthesis, endoprosthetic reconstruction, arthrodesis, and rotationplasty. The anatomic location of a tumor with the peroneal nerve proximity and the popliteal vessels soft tissue coverage is a problem. In addition, achieving the extensor mechanism is a big challenge due to the reattachment of the ligamentum patella. (4,7)

Endoprosthetic reconstruction is the main choice after tumor resection with a good functional outcome. Achieving the extensor mechanism is the major challenge post proximal tibia endoprosthetic reconstruction. Extension lag is the major challenge postoperatively. Several surgical techniques have been used to overcome this lag. (4,8,9)The main advantage of the endoprosthesis is the cost-effectiveness, good knee function, and ambulation without assistance. The energy expenditure in walking with an amputated knee with the prosthesis is more than a limb post endoprosthetic reconstruction. (7)There is a mechanical complication like aseptic loosening, structural failure, soft tissue failure and high rates of infection. (4,10) Extension lag means the inability of the muscle to actively achieve the passive limit of the joint. The body is positioned in such a way that the gravity is the sole external resistance to do the active movement. (11)

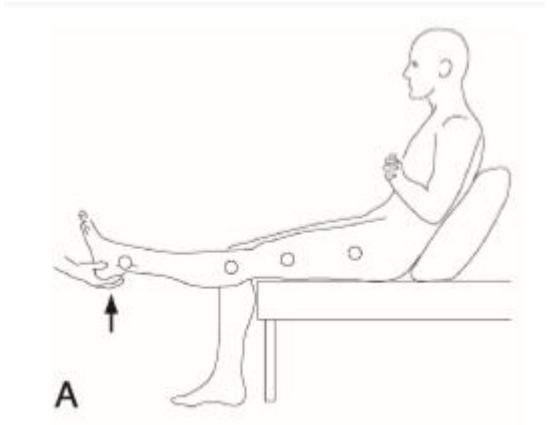


Figure 1 Extensor lag- patient unable to reach passive limit actively (11)

Extensor lag may be physiological lag or pathological lag (11,12) In normal healthy individuals, there is a 2.0 to 10.5 degree lag within 0 to 5 sec when asking the patient to hold against gravity showing that the rectus femoris muscle undergoes active insufficiency. This is because when the muscle contracts concentrically the maximum contraction tension decreases. (11) Pain, joint stiffness and joint distension are the other causes for the extensor lag. (12) Pathological lag may be due to various causes including arthrogenious muscle inhibition, soft tissue and bone damage following knee surgeries.(13,14,15)

Endoprosthetic tumor surgery

Limb salvage has lead to the development of megaprosthesis. The use of megaprosthesis in the proximal tibia always challenges the extensor mechanism of the knee joint due to the reinsertion method of the patellar tendon. The mean extensor lag in tibia megaprosthesis is reported to be 7.5 degrees to 24 degrees to 53 degrees extension lag in patients who have undergone replacement of patellar graft with gastrocnemius muscle. (9)

Musculo-Skeletal Tumour Society (MSTS) Score

The MSTS questionnaire is a well-accepted scoring system which measures the functional outcome after surgery. It has a descriptive grading from 1 to 5 pain, general function, emotional acceptance and specific function for lower extremity (walking ability, gait, supports). Each item is rated on a scale of 0 to 5. The total score ranges from 0 to 30, with higher scores indicating better function. In most studies, the result is expressed in percentage. The amputation of lower limb has a low MSTS score than a limb salvage procedure. (10)

Rehabilitation guidelines and protocols

Rehabilitation goals for a cancer patient are mainly two categories; restorative (returning to independent function level) and supportive (regaining partial independence in daily activities

with improved quality of movement). Restorative is the major goal for rehabilitation following EPRPT. Literature has shown five years of survival following lower limb endoprosthetic surgery. (17) Early gait training and reduced length of stay in the hospital contributes to successful early rehabilitation. Early rehabilitation improves the range of motion, muscle strength and overall quality of life. Successful early rehabilitation protocols are not clear and are debatable. (14–16) Acute rehabilitation protocols for endoprosthetic proximal tibia megaprosthesis are unpublished and undocumented. Proper protocols with particular anatomical description are not mentioned in literature. Only case reports are available giving descriptive guidelines about gait training, isometric and active assisted knee ROM after 6 weeks of prolonged immobilization with a brace. (17)

1.1 BACKGROUND AND NEED FOR THE STUDY

Limb salvage surgery using megaprostheses is the surgical procedure of choice for local control of malignant bone tumors in more than 90% of patients. (7,8) Numerous studies have reported 67 – 90% endoprosthetic survival in the lower limbs five years following surgery. The overall patient survival ranges from 60% to 70%. Furthermore, several studies confirm the efficacy and success of endoprosthetic replacement as a limb-sparing technique for the treatment of osteosarcoma and other malignant bone tumors. (9)

However, the functional status after megaprosthetic reconstruction around the knee is strongly dependent on the competence of the knee extensor mechanism. Kendall et al. reported that the functional deficits were mainly the result of a compromised extensor mechanism (17). Since gaining acceptable gait capability is by far the primary outcome sought by physicians and therapists, rehabilitation programs are often focused on walking exercises.

Early mobilization and gait training are reported as important factors essential to assure successful rehabilitation.(14) However there are no reports on the outcomes following early

supervised rehabilitation once the surgery is performed. Therefore in this study we aim to find out if early supervised rehabilitation in patients with EPRPT improves knee joint function and mobility and if there is any change in the outcomes at 3 months follow-up.

2. AIMS AND OBJECTIVES

2.1 Aims

- To assess the change in MSTS score and Knee ROM with early supervised rehabilitation in patients with EPRPT
- To find out there is any change in the outcomes at 3 months follow-up.

2.2 Objectives

- To investigate the effect of early supervised rehabilitation in patients with EPRPT.
- To evaluate if there is any change in the outcomes at 3 months follow-up.

3. REVIEW OF LITERATURE

The present study to investigate the efficacy of early rehabilitation in patients who underwent EPRPT was done after reviewing the following literature.

3.1 Bone tumor: Incidence & Epidemiology

Kindblom LG et al (2009) and Heare T et al (2009) reported the incidence of bone sarcoma as only 0.2% of all neoplasms. Primary malignant bone tumors are approximately 6 % of all childhood malignancies. When compared to the incidence rate of bone sarcoma to the soft tissue sarcoma the osseous neoplasm occurs at a rate of one-tenth of soft tissue sarcomas. More than 75% of malignant bone tumors are osteosarcoma, chondrosarcoma, and Ewing's sarcoma. (1, 5)

Osteosarcoma has an incidence of 0.3 per 100000 per year. This incidence is higher in adolescents at age 15-19 years. Boys are more affected than the girls. 80% of this sarcoma occurs in the extremities being more in the distal femur, proximal tibia, and proximal humerus. (5) Chondrosarcoma is a bone sarcoma of adulthood diagnosed at an age between 30 and 60 years. (1)

Ewing's sarcoma is a malignant tumor seen in adolescent and adult. The age of diagnosis is 15 years and males are more affected. The site is distributed between axial and appendicular with diaphysis the typical location. (5) Giant cell tumor of the bone is benign. It is locally aggressive and very rarely metatstatic. The incidence is 1 per million per year. Peak age is 5-30 and occurs in long bones of lower and upper extremities. (1)

Franchi A et al (2012) reported the cumulative risk of male deaths from cancer is 0.5% and among female is 0.4%. Males have a lesser survival rate than the female. (2)

3.2 Proximal tibial tumors & management

Albergo JL et al (2017) reported that endoprosthetic reconstruction of the proximal tibia has weight bearing advantage in early postoperative period restoring function. Use of biological reconstruction restores bone stock. Allograft is a good option for patients who are younger to achieve restoration of function and the limb length discrepancy is not seen while older population with poor prognosis where ambulation and return to function is needed faster endoprosthetic reconstruction is a better option. (20)

Puri et al (2014) have reported proximal tibia as the second most site for primary malignant tumors. Various surgical intervention includes endoprosthetic replacement, osteochondral allograft or arthrodesis following resection. Among the available option, EPRPT is the main standby in limb salvage surgery for reconstruction after tumor resection with excellent functions.(8)

Gkavardina A et al (2014) reported that for reconstruction after resection of primary malignant bone tumors, megaprosthesis is the better-established choice. Megaprosthesis achieves good disease control, facilitates early administration of adjuvant therapy and provide a stable, functional and durable extremity. Prosthesis design has evolved from the monoblock and fixed hinge models to modular endoprostheses and rotating platforms, with improved geometry to enhance fixation and stability (10)

Natrajan M V et al (2003) reported the establishment of limb salvage surgery over amputation. Management of proximal tibial tumors is a big challenge due to lack of muscles available and insufficient soft tissue for covering. Rotation plasty is successful among children. Resection arthrodesis achieves good stability but the knee functions are

compromised. Osteochondral allograft is used for benign and low-grade malignant tumors but the rate of complication is high. Amidst this challenge, EPRPT is the best method to treat malignant tumors with an acceptable rate of complication and a good knee function. (7)

3.3 Various Surgical procedure and approach in proximal tibia to reconstruct extensor mechanism

Ajay Puri (2014) has explained a technique for EPRPT through anteromedial approach extending from distal femur to anteromedial tibia which is an excellent exposure of vessels, fibula, and medial gastrocnemius muscle..The patella tendon is sutured using ethibond and a bone plug is wedged to hook the patellar tendon. This provides a strong lever arm for knee extension. Medial gastrocnemius muscle used as a flap. Recently a mesh is used which wraps circumferentially around proximal tibial prosthesis at the site of patellar anchorage. This circumferential fibrosis serves as mechanical pulley aiding the extensor mechanism of knee. (8)

Titus V et al (2008) explained the surgical procedure where the patellar ligament is reattached to the proximal tibial tuberosity on the prosthesis using porous-coated, nonabsorbable sutures around and through the ligament. The level at which the ligament is sutured to the prosthetic tibial tuberosity is based on the appropriate height relative to the trochlear groove where a ROM of 0 to 120 degree is achieved. The tension on the repair is reduced by placing a wire through the patella and through the hole in the prosthetic tibial tuberosity, causing a strain on the patellar ligament resulting in a Baja of patella which is temporary. Flaps were used only when there is a skin loss during primary closure. (9)

Martin Malwar (2004) explained three major steps for proximal tibial tumor – resection of a tumour, reconstruction of the skeletal defect and using modular prosthesis and reconstruction of extensor mechanism and soft-tissue coverage with medial gastrocnemius flap. A long medial incision is made from the medial peripatellar to the distal one-third of the leg. Tibia is removed along with muscles inserting on the tibia, popliteus muscle and extraarticular resection of the proximal tibiofibular joint is done. Peroneal nerve is preserved. Primary arthrodesis, prosthetic replacement, or allograft replacement. The key success of this procedure is the use of a gastronomies muscle transfer to obtain reliable soft-tissue coverage that helps prevent skin infection. (21)

3.4 Extensor lag in proximal tibia megaprostheisis

Pilge H et al (2015) and Kollender Y et al (2004) mentioned that resection of the proximal tibial tumours resulting in the excision of tibial tuberosity needed to have a reconstruction of the functional knee extensor mechanism. The need for reconstruction of the extensor mechanism is to restore active knee extension. A pre-tensioned, stable biomechanical fixation of the extensor mechanism to the proximal tibia is the key to a good functional outcome. Active knee extension is always compromised and extensor lag is a common problem after proximal tibial reconstruction.(4, 22)

Mavrogenis AF et al (2012) and Titus et al (2008) mentioned in periarticular knee resection, due to lack of soft tissues available and reattach the extensor mechanism is a big challenge thereby reduces the postoperative function and stability of the knee. Reconstruction of the extensor mechanism after resection in proximal tibia is a major challenge.(23, 9)

3.5 Influence of position of patella in extensor mechanism

Lenhart RL et al (2017) mentioned that superiorly displaced patella or patella alta have been shown to have association with the knee extensor lag, due to this the knee is not able to reach its passive limit. This occurs as the patellar tendon moment arm is diminished.(24)

Pilge H et al (2015) reported about the correlation between patella alta , extensor lag and MSTS score in proximal tibial megaprosthesis. The extensor lag with patella alta was 17 degree when compared to patients with normal patella height who had a lag of 4 degree.(22)

Phillips CL et al (2010) Patella baja ,abnormally low patella may be observed with anterior knee pain and reduced knee flexion. (25)

3.6 Measurement of patella height

Pilge H et al (2015) measured the height of patella in a proximal tibial tumour resection using the Blackburne-Peel-index in which standard radiographs of the operated knee is taken.(25)

3.7 Protocols available for quadriceps strengthening

Mintken PE et al (2007) mentioned that for TKR immediate postoperative, day 1 bed exercise like ankle pumps, quadriceps set, gluteal sets, hip abduction, short arc and straight leg raise, knee range of motion and bed mobility is encouraged. From the second day until discharge active knee range of motion and terminal knee extension is encouraged. Ambulation distance is also progressed till discharge. Neuromuscular electrical stimulation is used in the initial phase for motor units recruitment in inhibited quadriceps. (26)

Ennad and loomis (2000) mention about 2 rehabilitation protocols. One was a delayed mobilization post operatively where cast was given in extension for 6 week and weight bearing was started. Isometric for hip and ankle dorsiflexion and plantar flexion was started

post operatively. After removal of cast knee range of motion was started. Second protocol drop adjustable drop lock brace is given in extension and weight bearing started. Isometric for lower limb, prone knee bending active 90 degree bending and passive extension, active hip abduction, adduction and extension in standing for first 6 weeks. After discontinuing of brace active knee flexion and extension was started.(46)

3.8 Rehabilitation protocols available for proximal tibia

Lovecchio N et al (2016) have mentioned about an instrumental gait analysis. The rehabilitation process is divided into strength training session which included quadriceps, gastrocnemius eccentric contraction training, adductor, peroneus strength and balance training using hydro kinesiotherapy. The surgical technique mentioned is total knee resection of distal femur megaprosthesis and tibial allograft composite and the case had undergone 4 revisions before the rehabilitation. (27)

Lovecchio N et al (2015) have mentioned about using closed chain exercise as an effective method for rehabilitation. Half- squats reduced compressive and shear forces after megaprosthesis up to 60-70°. Hip and knee had good movement pattern and arrangement of foot and ankle complex improved. The surgical technique mentioned is total knee resection of distal femur megaprosthesis and tibial allograft composite and the case had undergone 2 revisions before the rehabilitation. (28)

Ajay Puri (**2014)** has mentioned the need for supervised early rehabilitation to gain good knee function. The patients are immobilized in a knee back knee splint for 6 week immobilization. Flexion to 30 degrees is started post 6 weeks progressing to 90 degrees. Active knee extension is initiated between 8 to 10 weeks.(8)

Ahmad Shahadeh et al (2013) mentioned the rehabilitation protocols following proximal tibia megaprosthesis. Immediate post-op period for 1 to 5 days the limb is kept elevated in rigid knee immobilizer (or long leg cast), ankle active range of motion exercise is started and weigh bearing is started as tolerated by the patient. From 6th day up to 6 weeks, only isometric quads are initiated. Active knee range of movement is restricted. Post 6 weeks active knee range of motion up to 90 degrees is initiated. Knee brace was worn during ambulation alone. The surgical technique used involved the use of bone graft, woven Dacron tape rotational medial gastrocnemius muscle flap coverage but exercise protocols for proximal tibia reconstruction surgery using megaprosthesis not used. (17)

3.9 Psychometric properties of the outcome measure

MSTS score

Xu et al (2017) reported MSTS scoring system is a disease-specific score which checks the mental and physical health for patients with extremity sarcoma. The Chinese MSTS scoring system is reliable with ICC of 0.91 test retest reliability and 0.90 for inter-observer analysis. The test for internal consistency is 0.86 as Cronbach's α. The application of the Chinese MSTS shows that the function and quality of life of limb salvage is better than amputation surgery. (16)

Iwata et al (2016) Test Retest analysis had a high inter class correlation coefficient (0.92). This indicates high reliability of the Japanese version of MSTS. Criterion validity showed a high correlation of MSTS scoring with TESS and SF- 36 physical components.MSTS is highly reliable and it measures the functional outcome for musculoskeletal tumors. (29)

Gkavardina A et al (2014) reported that MSTS is the mostly used score which measures the functional outcomes.It is widely validated tool.(10)

Rebolledo et al (2013) reported that MSTS was translated and culturally adapted to Brazilian Portuguese. This scale is reliable showing good internal consistency (0.84 as Cronbach's α), ICC of 0.92 retest reliability and 0.98 for inter-observer analysis. The validity of Brazilian MSTS rating was proved to be moderate with TESS and good discriminate validity. (31)

Ahmad Shahadeh et al (2013) followed the patients prospectively to assess the functional outcome using modified MSTS-ISOLS(Muskculoskeletal Tumour Society-Internal System on Limb Salavage) which is a validated tool used for measuring the functional outcome in limb salavage procedure.(17)

Manual muscle testing for muscle strength

Manual muscle testing is the most used tool in clinical set up to document the impairement of muscle strength. Kappa coefficient ranged from 0.63 to 0.98 for individual muscle and 0.57 to 1 for total MMT (sum of scores of individual muscle).The content validity of MMT is good because the test content is based on the physiological,anatomical and kinesiological principle.Bohannon in his study to compare the MMT and hand held dynamometer measurement of knee extensor streength in 128 acute knee rehabilitation showed high correlation $r=0.768$ $p<0.05$(25)

Knee range of motion

Golgia examined the inter rater reliability and validity of flexion measures and extension measures of knee in 30 healthy adult and reported inter-rater reliabity rannged from .98 to .99(Pearson's r) and .97 to .99 for validity supporting that the reliability and validity of goiniometer measurement of knee flexion.(32)

Mitchell and college studies on 20 individuals who were normal of affected with RA to measure knee flexion using the universal goniometer and found inter rater reliability r=0.96 with a error of 0.16 degree. (32)

Inter rater reliability for knee extension with goinimeter range from r=0.58 to 0.86. (32)

Passive knee extension test

Reurink et al (2013) reported ICC of 0.77 for passive knee extension test.(33)

Russell T Nelson et al (2004) reported inter class reliability of 0.98 in group of healthy individuals.(34)

6 Minute Walk Test

Mahamed Atef et al (2016) reported the test retest reliability in primary OA with ICC of 0.99(35)

Jakobsen et al (2013) reported reliability of 0.97 in total knee replacement patients.(36)

Kennedy et al (2005) reported excellent test retest reliability of ICC=0.94(32) in osteoarhthritis.(37)

4. METHODOLOGY

4.1 Method of the Study

4.1.1. Study Design

Pre test & Post test Experimental design

4.1.2. Study Setting

The data acquisition for the study was done in the Orthopaedic wards, and the Physiotherapy OPD of Christian Medical College, Vellore.

4.1.3. Study Duration

The duration for the study was 1 year.

4.1.4. Sampling

The sample for the study was selected using Convenience Sampling method. The sample size for the study was 6.

4.1.5. Ethical Approval

The study was approved by the ethics committee and the Institutional Review Board of Christian Medical College, Vellore. (IRB min No.11163)

4.2. Criteria for Selection

4.2.1. Inclusion criteria:

- Subjects who have undergone proximal tibia endo-prosthetic reconstruction for proximal tibia tumors
- Both gender
- Age between 20 to 40 years

4.2.2. Exclusion criteria:

- Fixation not strong enough to participate in an exercise program

- Total tibia tumor
- Significant removal of the quadriceps muscle
- Significant neurological involvement
- Hip ankle pathology

4.3 Variables

4.3.2. Study variables

Primary Outcome measures

- Knee ROM
- MSTS score

Secondary Outcome measures

- Hamstring tightness
- Muscle girth
- Knee muscle power
- 6 min walk test

4.4 Tools & Materials

4.4.1. Tools

a) **Goniometer** - It is an instrument which measures the range of motion / joint angles of the body. This tool is highly reliable and valid to measure the knee range of motion in the pathological condition. (33)

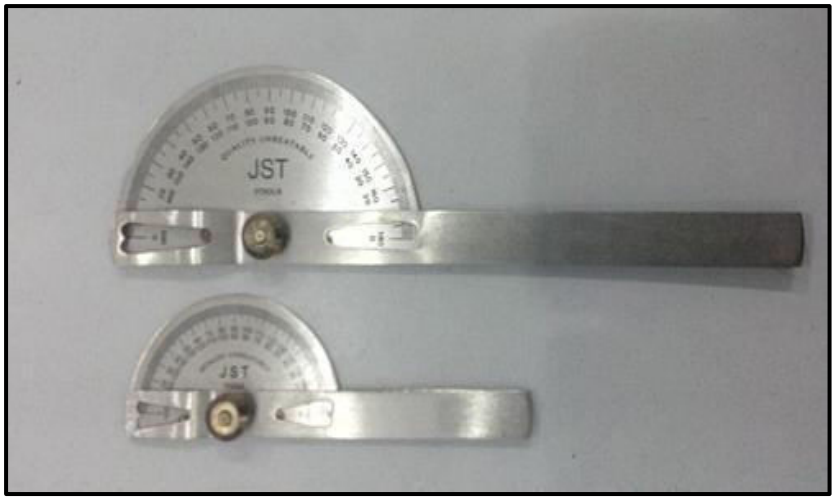


Fig. 2. Goniometer

b) **MSTS scale**– Musculoskeletal Tumour Society rating system for lower extremity evaluates pain, general function, emotional acceptance and specific function (walking ability, gait, and supports) is a widely accepted scale for tumor cases. Each category is scored from 0 to 5, for a total maximum score of 30, which is typically converted to a percentage. (14) (10)

SCORE	PAIN	FUNCTION	EMOTIONAL	SUPPORTS	WALKING	GAIT	Final Patient Score of FUNCTIONAL EVALUATIO
5	No pain	No restriction	Enthused	None	Unlimited	Normal	
4	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	
3	Modest/Non-disabling	Recreational restriction	Satisfied	Brace	Limited	Minor cosmetic	
2	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	
1	Moderate/Disabling	Partial restriction	Accepts	One cane or crutch	Inside only	Major cosmetic	
0	Severe disabling	Total restriction	Dislikes	Two canes or crutches	Not independent	Major handicap	
Patient score							

Fig. 3. MSTS Scale

c) **Nonelastic inch tape**

Fig. 4. Non elastic inch tape

4.4.2. Materials

a) Electrical stimulator

Fig. 5. Electrical Stimulator

4.5 Hypothesis

HYPOTHESIS 1

Null Hypothesis (H_0): There will be no improvement in patients with EPRPT with respect to MSTS score and knee ROM following early supervised rehabilitation.

Alternative Hypothesis (H_1): Early supervised rehabilitation in patients with EPRPT will result in significant improvement in MSTS score and knee ROM.

HYPOTHESIS 2

Null Hypothesis (H_0): There will be no improvement in outcomes at 3 months follow-up following early supervised rehabilitation.

Alternative Hypothesis (H_1): There will be significant change in outcomes at 3 months follow-up following early supervised rehabilitation.

4.6 Procedure for the Study

All subjects posted for proximal tumor endoprosthetic reconstruction surgery at CMC, Vellore were assessed for eligibility. Written consent was obtained by the principal investigator from all the 6 subjects who fulfilled the eligibility criteria. The subjects were assessed pre-operatively by the principal investigator for MSTS score, knee range of motion (ROM), knee muscle power, limb girth, tightness at knee and 6-minute walk test. All the measurements were assessed on the affected extremity.

MSTS scores were assessed using clinical interview and questionnaire method about the patient's pain level, emotional acceptance, and their functional independence. The MSTS score was measured at pre operative day, 3rd postoperative day, 1st week, 2nd week, 3rd week, 4th week and 3rd month**.**

Knee range of motion for extension was measured using goniometer in sitting position. Knee range of motion pre operative day, 3rd postoperative day, 1st week, 2nd week, 3rd week, 4th week and 3rd month**.** For extension, the goniometer axis was placed on the lateral epicondyle of femur. The stationary arm was placed on lateral midline of femur pointed towards greater trochanter and movable arm on the lateral part of the fibula in line with the lateral malleolus.

The patient was instructed to extend the knee. For flexion the patient was positioned in prone, with the same placement of goniometer the patient was instructed to bend the knee.

Thigh and calf girth measurement was done using a nonelastic inch tape. The girth measurement was done on pre operative day, 1st week, 2nd week, 3rd week, 4th week and 3rd month**.** The patient was positioned in supine. The joint line on the lateral side of the knee was marked in pen. For measuring thigh girth the joint line a distance of 15 cm was marked. For calf girth identify the largest girth, from the joint line a distance of 15cm was marked. For the measurement the inch tape was placed over the marked area around the girth of the thigh and calf.

Hamstring tightness was measured using passive knee extension test. This was measured on pre operative day, 1st week, 2nd week, 3rd week, 4th week and 3rd month**.** The goniometer was used to measure the passive knee extension test. Axis was placed at the lateral epicondyle of the femur. The moving arm was pointing towards lateral malleolus and the stationary arm was pointing towards greater trochanter. The patient was positioned supine; the hip was placed in 90 degrees of flexion. The opposite leg flat on a table, the knee was extended up to maximal tolerable stretch of hamstring muscle. The knee angle was measured.

The knee extensor muscle power was tested in high sitting and knee flexor muscle power was tested in prone lying. For knee extensor muscle power the patient positioned in sitting with the knee over the side of the table and the knee held close to the table. For fixation the examiner was holding the thigh firmly towards the table. The patient was instructed to extend the knee without rotation of the thigh. Pressure was given against the leg, above the ankle against the direction of flexion. For knee flexor muscle power the patient was positioned in prone lying. For fixation the thigh was held firmly down the table. Flex the knee between 50 degree and 70 degree. Pressure was applied proximal to the ankle in the direction of knee extension.

6 Minute Walk Test was used to assess the patients walking ability and endurance level of the individual. The test was conducted in a hallway of 20m distance. Two cones were placed 20m apart. The patient was asked to cover the distance at own pace in 6 minutes.

The surgical procedure involved the resection of a proximal tumor and the patellar ligament is reattached to proximal tibial tuberosity using porous-coated, nonabsorbable sutures around and through the ligament. The tension on the repair was reduced by placing a wire through the patella and hole of the tibial tuberosity.

After the reconstruction, on the 3rd post op day the knee ROM, the strength of the knee muscle and MSTS score was assessed again. From the 3rd post op day the patient received one session of supervised physiotherapy for 45 minutes. Assessment was done at the end of each week up to 1 month and follow-up assessment was done at 3 months post surgery. The data obtained was analyzed to find out if outcomes improved with early supervised rehabilitation in patients with the endoprosthetic reconstruction of the proximal tibia. The follow-up data was analyzed to find out if there was improvement in outcomes after 3 months post surgery.

4.6.1 Exercise Protocol:

4.6.2 Pre-op exercises:

- Isometric contraction for quadriceps muscle was taught with the ankle in dorsiflexion in long sitting.
- Isometric contraction of quadriceps with a towel roll under the ankle was taught in long sitting.
- Isometric hamstrings were taught in supine lying with knee bend to 30 degrees.
- Supine straight leg raise, side straight leg raise, and prone straight leg raise were taught.

- Short arc quadriceps was taught.
- Dynamic quadriceps in high sitting was taught.
- Patient was asked to hold for 5 sec with a rest period of 5 minutes to avoid fatigue. The exercise was repeated for 10 times.

Fig.6. Pre op training

4.6.3 Post-op 3rd day to 1 week:

- Isometric contraction for Quadriceps, hamstrings, and gluteus.
- Stimulation was given for the quadriceps muscle if not recruited.
- Ankle pumps were done.
- The knee range of motion was encouraged actively if the patient was not able to achieve active movements the therapist passively assist in the knee range.
- For knee flexion range initially, pillows are placed below the calf starting from 15°, 30°, 60°, and 90°. By the end of 1st week, 90 degrees of range of motion is achieved actively.
- Dynamic quadriceps in high sitting was encouraged actively from day 3.

Fig.6. Supervised rehabilitation

4.6.4 Post-op 1st week to 4th week:

- The same exercise as the first week was followed.
- Surgical tube of 3 mm was used for strengthening the ankle dorsiflexion, plantar flexion, inversion, and eversion.
- Short arc quadriceps was started.
- Dynamic quadriceps with a surgical tube of 3 mm is started.
- Hamstrings and tendo Achilles muscle was stretched using a towel with a hold of 10 sec for 10 counts.
- Gait training was started from the 10th day with bilateral axillary crutch starting with standing for a few minutes followed by ambulation inside the room followed by a gradual increase in distance.

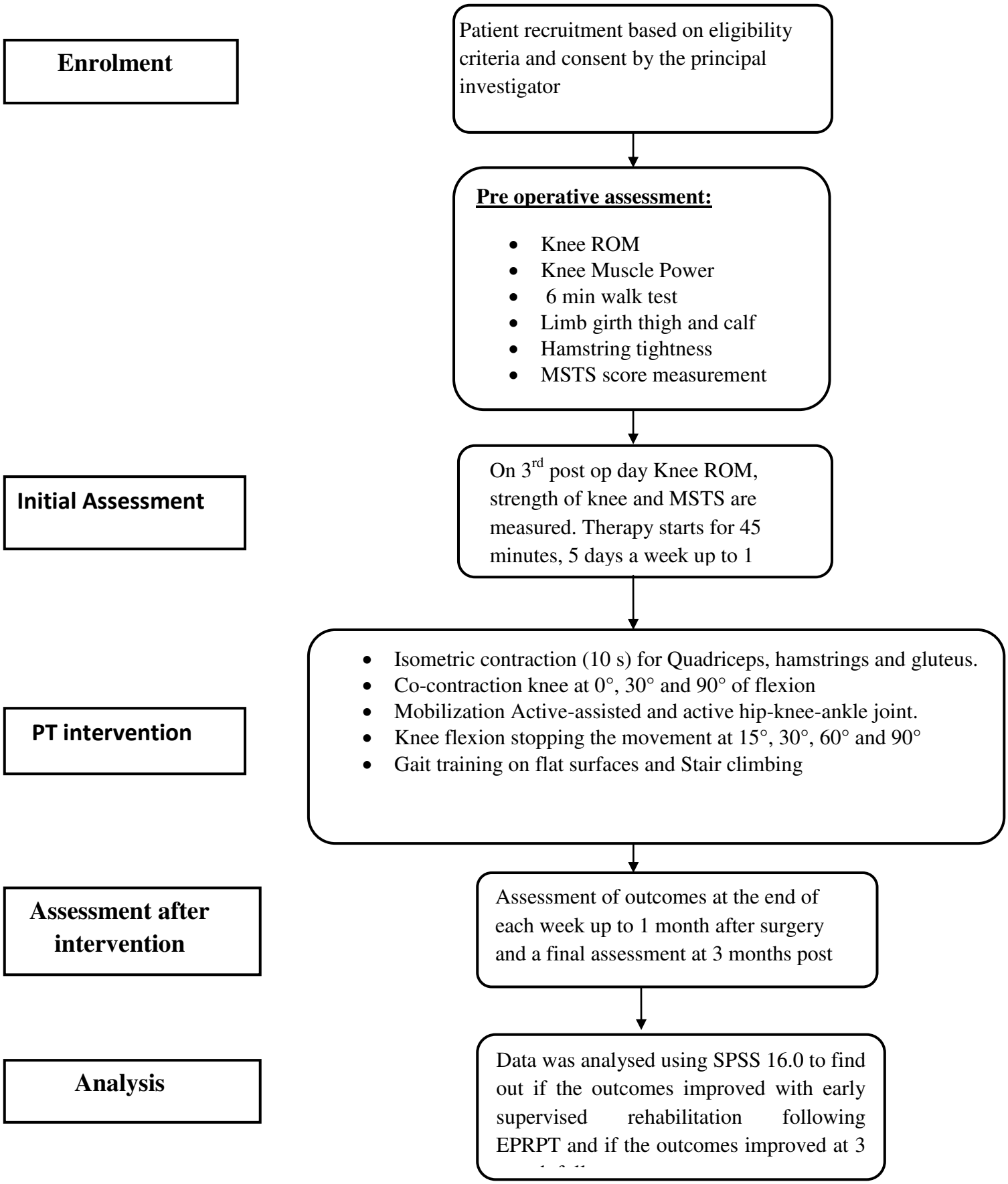
Fig.7. Patient Performing active Left Knee Extension at 3rd month follow up Post EPRPT

4.7 STATISTICAL ANALYSIS

The data was entered using EpiData. Means and standard deviations were computed for continuous variables and frequencies and Percentage for categorical variables. For skewed variables the data was summarized using Median and IQR. For all the analysis, p value<0.05 was considered to be significant. All the statistical analysis was done using SPSS version 16.0

Correlation analysis was used to find the strength between continuous variable. The Generalized Estimating Equation procedure was used to find the relationship between the follow up data. The Wilcoxon signed-rank test is a non-parametric statistical hypothesis test used to compare two related samples, matched samples, or repeated measurements on a single sample to assess whether their population mean ranks differ (i.e. it is a paired difference test).

4.8 Algorithm of the study:



5. DATA ANALYSIS AND INTERPRETATION

Descriptive statistics

Table 1. Tumour types across Gender, Age, Side affected, grade of tumour, type of prosthesis and no of pre op chemo.

Gender	Age (years)	Tumour Type	Affected Side	Grade of tumour	Type of prosthesis	No of pre op chemo
Male	34	Osteosarcoma	Right	High grade	Hinge	3
Male	18	Osteosarcoma	Left	High grade	Hinge	3
Male	23	Giant Cell Tumor	Right	NA	Hinge	0
Female	14	Osteosarcoma	Left	High grade	Hinge	4
Male	25	Ewing's Sarcoma	Right	High grade	Rotating hinge	3
Female	43	Gaint Cell Tumor	Right	NA	Hinge	0

NA- Not Available

Table 2. Demographic variables frequency

Variables	N	%
Gender		
Male	**4**	**66.6**
Female	**2**	**33.3**
Side		
Right	**4**	**66.6**
Left	**2**	**33.3**
Diagnosis		
Osteosarcoma	**3**	**50**
Ewing's sarcoma	**1**	**16.6**
Giant cell tumour	**2**	**33.3**
Grade of tumour		
High grade	**4**	**66.6**
Type of prosthesis		
Hinge prosthesis	**5**	**83.3**
Rotating hinge	**1**	**16.6**
Surgery done		
Tumour excision+Megaprosthesis	**6**	**100**
Flap	**6**	**100**
No of pre op chemo(cycles)	**3**	**75**
	4	**25**
Name of pre op chemo drug		
Inj Cisplatin+Adriamycin	**3**	**75**
Position of patella		
Baja	**4**	**66.6**
Normal	**2**	**33.3**
Age (Years)		
Mean(SD)	**26.17±10.68**	
Blackburne Peel Ratio(ratio)		
Mean(SD)	**.580±.258**	

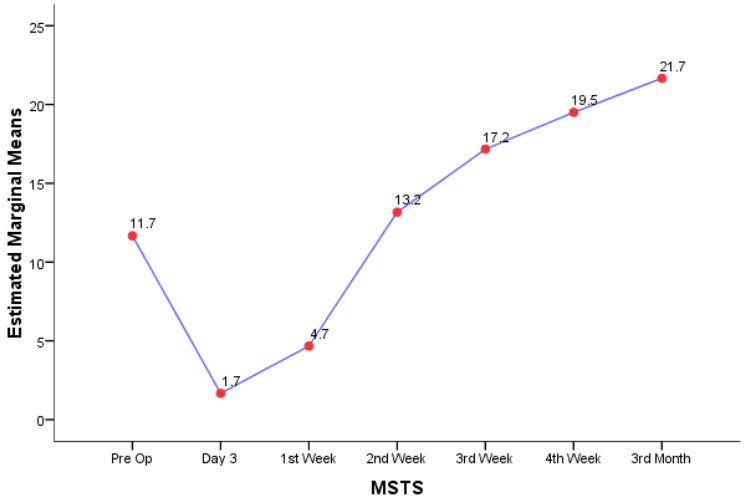
Table 3.Median (IQR), Mean (±SD), of MSTS score, Knee ROM Flexion and Extension, Knee Flexor and extensor muscle power, Hamstring tightness, Mid thigh girth, Mid calf girth and 6Min Walk Test of the entire sample at different assessment interval.

Outcomes	Pre-op	3rd POD	1st week	2nd week	3rd week	4th week	3rd months
MSTS							
Mean (SD)	11.67(4.41)	1.67(1.63)	4.67(1.86)	13.17(13.17)	17.17(4.16)	19.50(5.85)	21.67(3.01)
Median (IQR)	12(8,16)	1.50(.00, 3.25)	4(3,7)	12.50(9,18)	18.5(12,21)	22.5(12,24)	12(19.75, 24)
Knee ROM Flex(degree)							
Mean (SD)	118.50(17.36)	60(18.97)	65(13.78)	73.33(15.05)	80(10.95)	76.67(20.65)	76.67(20.65)
Median (IQR)	125(102, 131.25)	85(40,80)	65(50,80)	70(60,90)	80(70,90)	90(50,90)	90(50,90)
Knee ROM Ext(degree)							
Mean ((SD)	.00(.00)	18.33(22.28)	10(16.73)	7.50(14.05)	6.67(12.11)	8.33(13.29)	8.33(13.29)
Median(IQR)	.00(.00)	.00(.00, 25)	. .00(.00, 25)	. .00(.00, 16.25)	.00(.00, 15)	.00(.00, 22.5)	.00(.00, 22.5)
Knee MusPowFlex							
Mean (SD)	3.50(.83)	1.67(.51)	2.50(.54)	2.50(.54)	3(.63)	3.50(.54)	3.83(.40)
Median (IQR)	3(3,4.25)	2(1,2)	3(2,3)	3(2.75,3)	3.50(2.74,4)	4(3.75,4)	4(3.75,4)
Knee MusPowExt							
Mean (SD)	3.17(.75)	1.67(.51)	2.67(.51)	2.83(.40)	3.33(.81)	3.83(.40)	3.83(.40)
Median (IQR)	3(2.75,4)	2(1,2)	2.50(2,3)	2.50(2,3)	3(2.75,3.25)	3.50(3,4)	4(3.75,4)
Tig Ham (degree)							
Mean (SD)	2.50(4.18)	*	.83(2.04)	3.50(3.98)	6.17(5.84)	9.33(7.55)	11.17(11.23)
Median (IQR)	.00(.00, 6.25)		.00(.00, 1.25)	2.5(.00, 8)	6(.00,11.25)	5(4.5, 18.5)	5(4.25, 22.5)
Mid thigh girth(cm)							
Mean (SD)	37(3.97)	*	37.52(3.83)	37.43(4.27)	36.93(4.10)	36.42(4.31)	35.33(3.98)
Median(IQR)	37.75(32.5, 39.87)		38(33.37, 40.65)	38.30(32.82,40.77)	37.5(32.65, 40.5	36.5(32.125, 40.5)	35.5(31.5, 39.25)
Mid calf girth(cm)							
Mean (SD)	35.58(2.61)	*	34.28(1.35)	33.4(1.12)	32.33(.96)	31.23(1.36)	30.73(1.41)
Median (IQR)	35(33.62, 37.75)		34.4(33.425, 35.25)	33.4(32.65, 34.25)	32.85(31.15, 33.025)	31.1(30, 32.55)	30.9(29.45, 32)
6 Min Walk Test(meters)							
Mean (SD)	96(55.49)	*	*	*	*	92.5(26.41)	158.33(93.2)
Median (IQR)						100(60, 116.25)	115(92.5, 262.5)

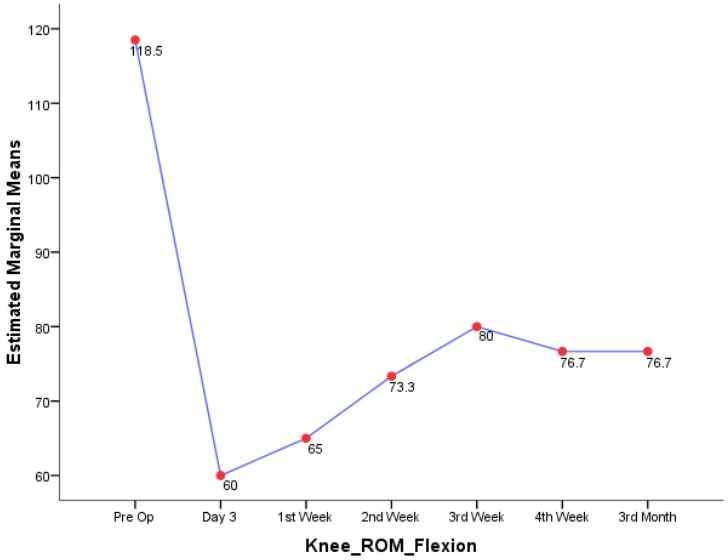
*Assessment was not done as the patients had a soft bandage around the operated knee.

MSTS-Musculoskeletal Tumour Society Scale,ROM –Range of Motion,Tig Hams-Tightness of hamstring, Knee MusPowFlex-Knee Flexor Muscle Power, Knee MusPowExt-Knee Extensor muscle Power.

Graph 1. Mean of MSTS scores at Various Points of Assessment



Graph 2.Mean Knee ROM of Flexion (in degrees) various points of assessment



Graph 3.Mean Knee ROM of Extension (in degrees) various points of assessment

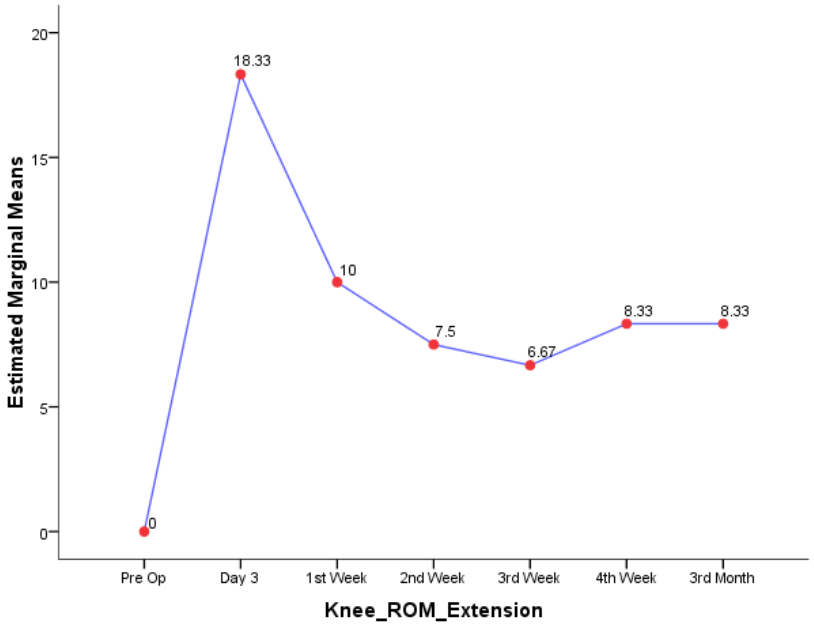


Table 4.Pearsons Correlation with MSTS and Knee ROM Flexion

Variables	Pearson Correlation	P value
MSTS vs Knee ROM Flex		
Pre Op	-.183	.729
3rd POD	.775	.070
1st Week	.623	.186
2nd Week	.905*	.013*
3rd Week	.832*	.040*
4th Week	.992*	0.01*
3rd Month	.815	.048*

*Statistically significant, (p value < 0.05)

Table 5.Pearson Correlation between MSTS and Knee ROM Extension

Variables	Pearson Correlation	P value
MSTS vs Knee ROM Ext		
Pre Op	.[a]	.
3rd POD	-.788	.063
1st Week	-.642	.169
2nd Week	-.580	.228
3rd Week	-.581	.226
4th Week	-.963**	.002*
3rd Month	-.916*	.010*

*Statistically significant, (p value < 0.05)

Table 6. Comparisons of MSTS, Knee ROM Flexion and Knee Flexor muscle power at 7 Assessment times.

Variables	Beta(b)	95%CI		p value
		Lower	Upper	
MSTS				
3rd Month	10.000	7.512	12.488	0.01*
4th Week	7.833	5.695	9.971	0.01*
3rd Week	5.500	4.214	6.786	0.01*
2nd Week	1.500	.392	2.608	.008*
1st Week	-7.000	-9.400	-4.600	0.01*
3rd POD	-10.000	-12.167	-7.833	0.01*
Baseline	Reference	.	.	.
Knee ROM Flex				
3rd Month	-41.833	105.817	-21.275	0.01*
4th Week	-41.833	-62.392	-21.275	0.01*
3rd Week	-38.500	-62.392	-21.440	0.01*
2nd Week	-45.167	-55.560	-27.272	0.01*
1st Week	-53.500	-63.061	-37.208	0.01*
3rd POD	-58.500	-69.792	-38.771	0.01*
Baseline	Reference 0[a]	.	.	.
Knee Mus Pow Flex				
3rd Month	.333	-.263	.930	.273
4th Week	-6.012E-17	-.800	.800	1.000
3rd Week	-.500	-1.266	.266	.201
2nd Week	-1.000	-1.800	-.200	.014*
1st Week	-1.000	-1.800	-.200	.014*
3rd POD	-1.833	-2.383	-1.283	0.01*
Baseline	Reference 0[a]	.	.	

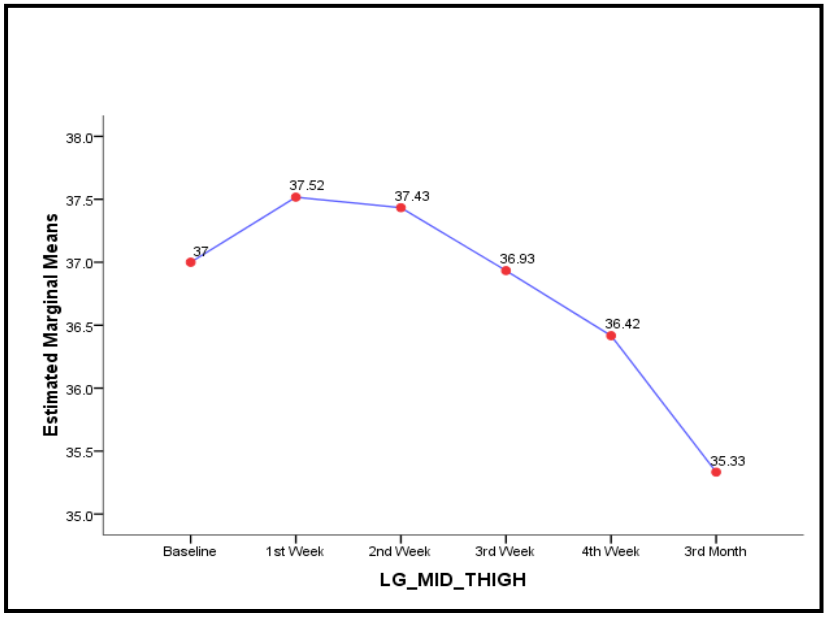
*Statistically significant, (p value < 0.05)

Table 7 Comparison of Knee ROM Extension and Knee Extensor muscle power at 7 Assessment times.

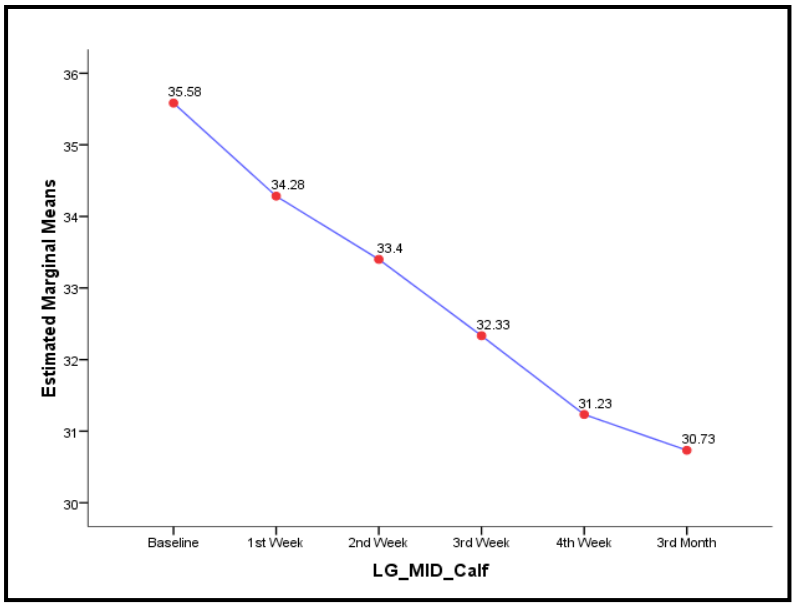
Variables	Beta(b)	95%CI		p value
		Lower	Upper	
Knee ROM Ext 3rd Month	8.333	-1.375	18.042	.093
4th Week	8.333	-1.375	18.042	.093
3rd Week	6.667	-2.179	15.513	.140
2nd Week	7.500	-2.765	17.765	.152
1st Week	10.000	-2.223	22.223	.109
3rd POD	18.333	2.055	34.612	.027*
Baseline	Reference 0	.	.	.
Knee Mus Pow Ext 3rd Month	.667	.070	1.263	.028*
4th Week	.667	.070	1.263	.028*
3rd Week	.167	-.687	1.021	.702
2nd Week	-.333	-.930	.263	.273
1st Week	-.500	-1.111	.111	.109
3rd POD	-1.500	-2.111	-.889	0.01*
Baseline	Reference 0	.	.	.

*Statistically significant, (p value < 0.05)

Graph 4. Mean limb girth of thigh various points of assessment



Graph 5. Mean limb girth of calf various points of assessment



Graph 6. Mean Hamstring tightness various points of assessment

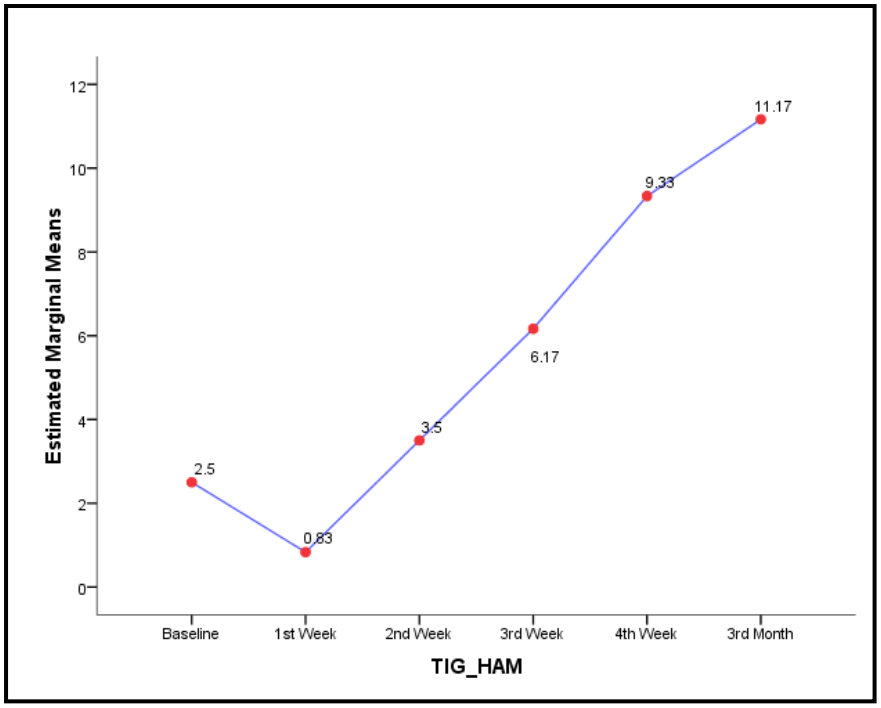


Table 8. Comparison of Mid thigh girth, mid calf girth and hamstring tightness at various assessment times.

Variables	Beta(b)	95%CI		p value
		Lower	Upper	
Mid thigh girth 3rd Month	-1.667	-2.489	-.845	0.01*
4th Week	-.583	-1.292	.125	.107
3rd Week	-.067	-.587	.453	.802
2nd Week	.433	-.004	.871	.052
1st Week	.517	.205	.828	.001*
Baseline	Reference 0	.	.	.
Mid calf girth 3rd Month	-4.850	-7.387	-2.313	0.01*
4th Week	-4.350	-6.827	-1.873	.001*
3rd Week	-3.250	-5.138	-1.362	.001*
2nd Week	-2.183	-3.620	-.746	.003*
1st Week	-1.300	-2.653	.053	.060
Baseline	Reference 0	.	.	.
Hams tig 3rd Month	8.667	3.467	13.866	.001*
4th Week	6.833	4.046	9.621	0.01*
3rd Week	3.667	.511	6.823	.023*
2nd Week	1.000	-2.457	4.457	.571
1st Week	-1.667	-3.553	.219	.083
Baseline	Reference 0	.	.	.

Table 9.Difference in 6 Min Walk Test at pre op, 4th week and 3rd month

Variables	Pre Op – 4th week		Pre Op – 3rd month		4th week –3rd month	
	z score	p value	z score	p value	z score	p value
6 Min Walk Test	-.271	.786	-2.023	.043*	-2.023	.043*

*Statistically significant, (p value < 0.05)

6. RESULTS

Six subjects with Proximal tibia tumour participated in this study after a written consent.

The participant characteristics has been described in Table 1. Out of the total 6 participants,4 were males and 2 females. The mean age of the sample was 26.17 ±10.68 years.

Table 2 provides frequencies of the categorical demographic data collected during the initial assessment.In this data Osteosarcomas (N=3), Ewing's sarcoma (N=1) and Giant cell Tumour(N=2) were diagnosed tumours. 66.6% had high grade tumour. Among the 6 subjects 66.6% were male subjects and the mean age was 26.17±10.68 . The right lower extremity was affected more than left with the ratio 2:1.

The surgical procedure undergone by all the subject was homogeneous that is tumour excision and megaprosthesis. All of them had flap used and 83.3% used hinge prosthesis and 16.6% had rotating hinge prosthesis. Except 2 all the participants had under gone pre operative chemotherapy cycle.Three of the subjects had 3 (75%) cycle of pre-operative chemotherapy and 1 subject had 4 (25%) cycle of preoperative chemotherapy. 75% of the medicine used for the chemotherapy cycle is Inj Cisplatin+Adriamycin. (Table 1) Among 6 subjects 66.6% had a patella baja and 33.3% had a normal patella.

Descriptive statistics was done to present the Median (inter quartile range) and Mean and Standard Deviation of MSTS score, Knee ROM Flexion and Extension, Knee Flexor and Extensor muscle power, Hamstring tightness, Mid thigh girth, Mid calf girth and 6Min Walk Test. The mean MSTS score, Knee flexion and extension range, knee extensor and flexor strength showed a progressive and consistent increase from 3rd post operative day to 4th week post EPRPT. (Table 3)

Table 4 presents Pearson Correlation between MSTS and Knee ROM Ext which shows significant correlation (p value < 0.05) at 2nd week to 4th week.

Table 5 presents Pearson Correlation between MSTS and Knee ROM Extension which shows significant correlation (p value < 0.05) at 4th week and 3rd month.

Table 6 which presents the comparisons of MSTS, Knee ROM Flexion and knee flexor muscle power at 7 assessment times there was marginal decrease by 1 units in the knee flexor muscle power from 3rd post operative day to 2nd week which is significant. Toward 3rd month there was minimal increase in muscle power which is not significant.

The comparison of Knee ROM Extension and Knee Extensor muscle power at 7 assessment times shows that Knee extensor muscle power from baseline to 3rd post operative day showed 1 unit decrease in the power which was significant. From 3rd week to 4th week there was 0.667 units increase in muscle power the effect remained till 3rd month which was significant statistically. (Table 7)

Table 8 presents the comparison of Mid thigh, mid calf girth and hamstring tightness at various assessment times showed that the hamstring tightness from 1st week to 2nd week increased by 1 unit. From 2nd week to 3rd week there was 3 units increase, from 3rd week to 4th week there was 6 units increase and from 4th week to 3rd month there was 8 units increase in hamstring tightness which was significant statistically. There was marginal reduction in the girth of the mid thigh and calf till 3rd month from baseline.

Table 9 presents the difference in 6 Min Walk Test at pre op, 4th week and 3rd month there was a significant improvement in the distance at 4th week and 3rd month from pre-operative distance.

7. DISCUSSION

This study was designed to find out the impact of early supervised rehabilitation in subjects who underwent EPRPT for proximal tibial tumours. A total of 6 subjects were eligible and were recruited after a written consent.

Knee ROM, limb girth of thigh and calf, tightness at knee, strength of the knee muscle, 6 minute walk test and MSTS score was assessed for each subject pre-operatively. Following EPRPT, the subjects were on early supervised rehabilitation from 3rd post-operative day till 4th week. Follow-up assessment was done at 3rd month post EPRPT.

Out of the total 6 participants, 4 were males (66.6%) and 2 females (33.3%) (Ratio=2:1) which supports epidemiological data. Males subjects are affected more than females as reported by **Alessandro Franchi (2012)**.(2) The mean age of the sample was 26.17 ±10.68 years (Table 2). Among the 6 subjects 4 were having high grade tumour showing that majority of Osteosarcoma is malignant tumours. The malignant bone tumours are age specific in age group of 10-40 years, peak incidence at 10-20 years primarily Ewing's sarcoma and Osteosarcoma, supporting the observation made by **Kindblom (2009)** (1) Tumour type included in sample showed 3 subjects with Osteosarcoma,1 subject with Ewing's sarcoma and 2 subject with Giant cell tumour. The Giant cell tumour around the knee is diagnosed at age of 20-40 years **Lin (2016**)(39). Further a preponderance of the right side over the left (2:1) was observed in the included participants as a secondary finding. 2 subjects with Giant cell tumour had the right knee affected this supported the data reported by **Lin (2016**)(39).The reason for such preponderance remains to be explored.

Only 4 subjects with Osteosarcoma and Ewing's Sarcoma underwent chemotherapy preoperatively with majority undergoing 3 cycles of chemotherapy. The drug used in the cycle was Cisplatin and Adriamyacin (Table 1). The adjuvant chemotherapy was used to

increase the cure rates of bone tumour which was reported to be around 66% for Osteosarcoma and Ewing's sarcoma **Natrajan (2003)**(7). Muscle weakness that is impaired ability of the muscle to produce force even after rest is one of the complication reported with chemotherapy in cancer patients. (39). No data is available if these drugs and number of preoperative cycles would affect the rehabilitation of the bone tumour around the knee.

83.3% subjects used the hinge prosthesis (Table 1 & 2).These hinged prosthesis were custom made in India. All the subjects underwent the tumour excision and megaprosthesis as reported by **Titus V(2008)** (9). Flap was used for all the patients mostly the gastronemius muscle flap, (Table 2) which has been reported to serve as a good bed for a split thickness graft and facilitate healing of the surgical site without infection. **Puri (2014)**(8)

Post-operatively based on the Blackburn Peel Ratio the position of the patella was baja (66.6%) and 33.3% had a normal patella. The position of patella being in baja post-operatively is reported previously in literature by **Titus V (2008)** (9).(Table 2)

The mean MSTS score was 1.67±1.63 on 3rd post-operative day which improved significantly to 21.67±3.01 by 3rd month (p value < 0.05). (Table 3) There was a continuous significant improvement, (p value < 0.05) in the MSTS scores from the 3rd post operative day. From the base line to 3rd post-operative day there was 10 units drop in score. From 3rd post-operative day to 1st week there was 7 units drop in score. (Table 6) This explains that the initial period there was severe pain, emotional acceptance was less and thereby the function and walking was not initiated. The progressive and unswerving improvement in MSTS scores from 1st week till 3rd month can be primarily attributable to the decrease in pain scores, improved emotional aspect of the disease, walking distance and improved gait with time. (Graph 1)

The mean Knee flexion range of motion at baseline was 118.50± 17.36 degrees which reduced to a mean of 76.67±20.65 degrees by the 4th week. (Table 3) The decrease in Knee

flexion ROM was significant in the first week, (Table 6) which may be due to the immediate post-operative pain and the alignment of patella in patella baja reducing the knee flexion which is supported by **Philips CL (2010)** showing similar decrease in Knee flexion in subjects with patella baja. (25)**.** From 1st week up to 4th week there is improvement in the range of flexion this shows that the supervised rehabilitation had reduced pain and the range improved over time. (Graph 2) There was no difference between 4th week and 3rd month (Table 6). (p value > 0.05) The possible reason for this is that the custom made prosthesis has a limited flexion range.

The mean Knee flexor muscle power was 3.50±0.83 at baseline which was achieved by the 3rd month (3.83±0.40). (p value > 0.05) (Table 3) Knee flexor muscle power from baseline there was 1 unit reduction on 3rd post operative day which was statistically significant (p value < 0.05).This is because of muscle inhibition post-operatively due to pain. From 1st week to 4th week there was no improvement in the knee flexion muscle power. (Table 6) **Jennifer.E (2010)** reported 39.4% deficit in hamstring strength 3 weeks post total knee replacement. There was an improvement of only 15.2% of hamstring deficit at 3 months. (42) Undergoing chemotherapy there is a reduction in the muscle property which can add on to the reason of not improving the strength of knee. (39)

The mean knee extension range of motion was 18±33 degrees on 3rd post operative day and by 4th week the mean was 8.33±13.29 degrees. (Table 3) Knee extension ROM from baseline to 3rd post operative day there is an 18 unit's increase which was significant (p value < 0.05) (Table 7). From 3rd post operative day to 1st week there was a 10 units increase showing early supervised rehabilitation significantly improves the knee range of motion (p value < 0.05) (Table 7). The Knee extension range gradually improved from 1st week till 4th week, no significant increase was noted in the 3rd month (p value > 0.05), which shows that the

supervised rehabilitation helps to improve range which is maintained at 3 months follow-up . (Graph 3).

The mean knee extensor muscle power was 3.17±.75 at the baseline and the power improved to 3.83±.0.40 at 3rd month. There was significant reduction in muscle Knee extensor muscle power from baseline to 3rd post operative day. From 3rd post-operative period to 2nd week there was marginal reduction in muscle power. From 2nd week to 3rd month there was progressive increase in muscle power (p value < 0.05). In form 4th week to 3rd month there was no change in the muscle power. **Jennifer.E (2010**) reported a 42.9% deficit in quadriceps strength 3 weeks after total knee replacement and 7.1% quadriceps deficit at 3 month. (41), Muscle power improved with supervised therapy towards 4th week which was maintained at the 3rd month follow-up.

In correlation between MSTS and Knee range of motion flexion there was significant relation from 2nd week to 3rd month (p value < 0.05).With the increase in MSTS score there is increase in knee flexion range (Table 4). In correlation between MSTS and knee range of motion extension there was a significant relation at 4th week and 3rd month.(p value < 0.05).(Table 5). With increase in MSTS score and knee extension range of motion decreased. The decreased knee extension at 4th week and 3rd month may be attributed to the hamstring tightness which was present in some subjects. **Jackson AS (2001)** reported that when the biomechanical function of the knee is restored the functional gain is large. Achieving a normalized gait pattern improves the physical function. With regular physiotherapy post-operatively for 3 weeks improved range of motion and function.(42)

The Mid thigh girth showed a mean of 37±3.97cms at the baseline which reduced to 35.33±3.98cms at 3rd month follow-up. (Table 3) **Capt (1998)** reported the decrease in girth measurement following surgery is associated with pain and effusion leading to inhibition and

disuse atrophy (44) (Table 8) From 4th week up to 3rd month there was not much reduction in the girth which is statistically not significant (p value > 0.05) shows that no significant atrophy of muscle have occurred supporting the need of early supervised rehabilitation.(Graph 4) (Table 8) In normal healthy subjects showed that the bed rest for a period of 5 to 6 weeks have increased the atrophy of the quadriceps muscle of knee and plantar flexors of the ankle. With training, recovery of the muscles can be achieved.(43)

At baseline the mean Mid calf girth was 35.58±2.61 which reduced to 30.73±1.41 by 3rd month. There is significant reduction in mid calf girth from baseline to 4th week (p value < 0.05). (Table 8) The immediate post-operative reduction in the girth of calf is associated with pain and effusion. The 3 unit reduction of calf in the 3rd week shows the disuse of the muscle functionally. There is marginal reduction from 4th week to 3rd month which shows there is functional improvement in the subjects with early rehabilitation.(9)

Baseline hamstring tightness was 2.50±4.18 which increased to 11.17±11.23 at 3rd month. (Table 3). Hamstring tightness there is mild increase from baseline to 4th week which is not significant. (p value > 0.05) From 3rd week to 4th week there was 6 units increase in tightness which is statistically significant. (p value < 0.05) From 4th week to 3rd month there is 8 unit increases in the hamstring tightness which is significant. (p value < 0.05) (Graph 6) (Table 8).This increase in tightness may be due to the complication of radiotherapy which the subjects had to undergo after 1 month.

There was no significant improvement in the 6 min walk test from at 4th week (Table 9). Extensor lag is the major complication post megaprosthesis reconstruction in proximal tibia.(9) Due to quadriceps weakness walking speed reduces. Patients adapt a stiff knee gait in TKR which shows that knee flexion is reduced and the load is more on the quadriceps muscle. Muscle coactivation is reported in patients with stroke, healthy individual old age

due decrease in muscle strength. Increase coactivity of the hamstring and quadriceps muscle postoperative due to weakness in muscle and pain leads to compensatory strategy in walking which affects the walking pattern and speed.(45). From pre-operative day to 3rd month there was significant improvement. (p value < 0.05) Between 4th week and 3rd month there was a significant improvement in distance which supports the need for early supervised rehabilitation. (p value < 0.05)

Our results show that early supervised rehabilitation may improve knee function and range in subjects who had undergone EPRPT. Early mobilization and gait training are reported as important factors essential to assure successful rehabilitation.(17) Our study is the first of its kind to report the progressive improvement in knee function following supervised physical therapy during the initial rehabilitation phase [0 to 3 months]. No prospective reports are available in literature which has documented the effects of supervised rehabilitation following proximal tibial reconstruction. Despite early supervised rehabilitation, hamstring tightness developed towards the end of rehabilitation.

8. SUMMARY & CONCLUSIONS

The following conclusions were made from the study **"Effect of early supervised rehabilitation on MusculoSkeletal Tumour Society Rating Score (MSTS) and knee range of motion (ROM) in subjects with endoprosthetic reconstruction of proximal tibia (EPRPT)" – Pilot Study**

1. Early and supervised physiotherapy post EPRPT significantly improved the MSTS score.
2. The knee range of motion improved significantly with early supervised rehabilitation.
3. The MSTS score and the Knee range of motion were maintained at 3rd month follow-up.

Proximal tibia is the second most common site for the bone osteosarcoma and giant cell tumor (Puchner SE,2015).(3)**.** Endoprosthetic replacement of proximal tibia is the best method to treat malignant tumors with an acceptable rate of complication and a good knee function (Natrajan, 2003) (10)**.** The reconstruction of the proximal tibia has weight bearing advantage in early post-operative period restoring function. (Albergo JL, 2017) (20) There was a gap in the literature on the effect of early supervised rehabilitation in subjects who underwent EPRPT in terms of mobility and function at the knee in the initial phase of rehabilitation immediate post surgery till 4th week. The rehabilitation protocols available was after 6 to 12 week of immobilisation the knee joint with brace not facilitating active range of knee motion and most studies were retrospective case reports.

Our results show that early supervised rehabilitation may improve knee function and range in subjects who have undergone EPRPT, during the initial phase of rehabilitation which is

maintained upto 3 months post EPRPT. Substantiation of the results with long-term follow-up is necessary to find the long-term effectiveness of early supervised rehabilitation. Adherence to therapy needs to be strongly recommended to maintain good functional life. However, further work is warranted to evaluate such a possibility.

9. LIMITATIONS & RECOMMENDATIONS

9.1 Limitations of the Study:

- The sample size which we got for this prospective study within a span of 1 year was too small to make any generalisations for the population.
- Pre-operative chemotherapy may induce fatigue and cause deconditioning which might affect the rehabilitation.
- The cost of the entire treatment including surgery, prosthesis, radiation & chemotherapy was a probable factor responsible for some subjects not opting for the surgery.
- Adherence to home program could not be ensured due to the logistic issues.

9.2 Future Recommendations:

- Prospective studies with a larger sample size needs to be undertaken in order to generalise the results.
- Substantiation with larger sample size and long term follow-up is required to find out the long term benefits.
- Adherence to the home program needs to be ensured for better results.
- Study on position of patella influencing the functional level of the patient can be explored in the future

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APPENDIX 1

Informed Consent Form

Study Title: ": "Effect of early supervised rehabilitation on Musculo Skeletal Tumor Society Rating Score (MSTS) and knee range of motion (ROM) in subjects with endoprosthetic reconstruction of proximal tibia (EPRPT)" – Pilot Study

Study Number: _____

Subject's Initials: _____

Subject's Name: _____

Date of Birth / Age: _____

(Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____ Signature:

Or

Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

Date: _____/_____/_____

Name & Address of the Witness: _____

APPENDIX 2

PARTICIPANT INFORMATION SHEET

To: Mr./Mrs./Ms_____

Dear Sir/Madam,

I hereby invite you to participate in the study, titled **"**: "Effect of early supervised rehabilitation on Musculo Skeletal Tumor Society Rating Score (MSTS) and knee range of motion (ROM) in subjects with endoprosthetic reconstruction of proximal tibia (EPRPT)" – Pilot Study.

In this study we aim to find out if early & supervised knee exercises in patients with tibia reconstruction surgery can cause improvement in the knee function and mobility.

The subjects who have been posted for EPRPT surgery will be assessed pre-operatively by the therapist for knee range of motion (ROM), limb circumference, position of the patella, tightness at hip, knee and ankle joints, strength of the quadriceps muscle and physical function score after a written consent. On the 3 rd day after surgery the same outcomes will be measured after which the supervised exercises will be given for 45 minutes one session per day for 5 days a week up to 1 month.

The therapist will do a regular assessment at the end of each week up to 1 month and follow-up assessment will be done at 3 months. This information collected will be analyzed to find out if the intervention given brought any improvement in the knee ROM and functional outcomes after 3 months post surgery

All the information and the data obtained in this study will be maintained and will be accessible only to authorized members involved in the study, to ensure confidentiality. Your participation in this study is completely voluntary and you may withdraw from the study at any time.
Your participation in this project shall be appreciated.

Yours sincerely,
Mrs.Maria Steffy
MPT student

APPENDIX 3

DATA COLLECTION SHEET

DATE OF ASSESSMENT:

DATE OF SURGERY:

- **General information:**

i. Name of the patient :
ii. Hospital no. :
iii. Gender :
iv. Age :
v. Side :

- **Relevant information**

i. Tumour type :
ii. Grade of tumour :
iii. No of pre op chemo :
iv. Name of pre op drug :
v. Type of prosthesis :
vi. Surgery done :
vi. Flap :
vii. Blackburne-Peel-Index :
viii. Position of patella :

ASSESSMENT

Outcome measures:

KNEE ROM & MUSCLE POWER ASSESSMENT

	ROM (Right) ((in ^{0})	ROM (Left) (in ^{0})
Flexion		
Extension		
	Muscle Power (Right)	Muscle Power (Left)
Flexion		
Extension		

LIMB GIRTH & TIGHTNESS

	Affected side
Mid-thigh (15cm from joint line)	
Mid-Calf (15 cm from joint line)	
Hamstrings	

6 MINUTE WALK TEST(METERS)

MSTS ASSESSMENT

SCORE	PAIN	FUNCTION	EMOTIONAL	SUPPORTS	WALKING	GAIT	Final Patient Score of FUNCTIONAL EVALUATIO
5	No pain	No restriction	Enthused	None	Unlimited	Normal	
4	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	
3	Modest/Non-disabling	Recreational restriction	Satisfied	Brace	Limited	Minor cosmetic	
2	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	
1	Moderate/Disabling	Partial restriction	Accepts	One cane or crutch	Inside only	Major cosmetic	
0	Severe disabling	Total restriction	Dislikes	Two canes or crutches	Not independent	Major handicap	
Patient score							

PAIN=

FUNCTION=

EMOTIONAL=

SUPPORT=

WALKING=

GAIT=

TOTAL=

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

September 19, 2018

Ms. Maria Steffy
Student,
Department of PMR,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant: New Proposal** :
Effect of early supervised rehabilitation on Musculo Skeletal Tumor Society Rating Score (MSTS) and knee range of motion (ROM) in subjects with endoprosthetic reconstruction of proximal tibia (EPRPT)" – Experimental study.
Ms. Maria Steffy Sumesh Kumar, MPT Student (2071843), 2071843), PMR, Department, Dr. V.T.K. Titus, Prof. in Orthopedics, HOD Employment no: 03556, Mr. Andrew Babu (Guide), Head of Physiotherapy, Ms. Merlyn Tilak (Co Guide) Lecturer (PT), Employment number: 38479, Ms. Grace Rebekah J Employment no: 32070, Lecturer (Grade II) Department of Biostatistics

Ref: IRB Min. No. 11309 [INTERVEN] dated 18.04.2018

Dear Ms. Maria Steffy,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., D.M.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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Ref: IRB Min. No. 11309 [INTERVEN] dated 18.04.2018

Dear Ms. Maria Steffy,

The Institutional Review Board (**Silver**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Effect of early supervised rehabilitation on Musculo Skeletal Tumor Society Rating Score (MSTS) and knee range of motion (ROM) in subjects with endoprosthetic reconstruction of proximal tibia (EPRPT)" – Experimental study" on April 18, 2018.

The Committee reviewed the following documents:

1. IRB Application format
2. Patient Information sheet and Informed Consent Form (English, Tamil, Hindi, Telugu and Bengali)
3. Proforma
4. Cvs of Ms. Maria Steffy Sumesh Kumar, Dr. V.T.K. Titus, Mr. Andrew Babu, Ms. Grace Rebekah J, Ms. Merlyn Tilak
5. No. of documents 1 – 4.

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

The following Institutional Review Board (Silver, Research & Ethics Committee) members were present at the meeting held on April 18th 2017 at 9.45 am in the New IRB Room, Christian Medical College, Bagayam, Vellore 632002.

Name	Qualification	Designation	Affiliation
Dr. George Thomas	MBBS, D Ortho, PhD	Orthopaedic Surgeon, St. Isabella Hospital, Chennai, Chairperson, Ethics Committee, IRB, Chennai	External, Clinician
Dr. Sridhar Gibikote	MBBS, DMRD, DNB	Professor, Radiology, CMC, Vellore	Internal, Clinician
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Additional Vice Principal (Research), Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore.	Internal, Clinician
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist &Epidemiologist
Prof. Keith Gomez	BSc, MA (S.W), M. Phil (Psychiatry Social Work)	Student counselor, Loyola College, Chennai, Deputy Chairperson, Ethics Committee, IRB	External, Lay Person & Social Scientist
Dr. P. Zachariah	MBBS, PhD	Retired Professor, Vellore	External, Clinician
Dr. RV. Shaji	B.Sc, M.Sc, PhD	Professor, Heamatology, CMC, Vellore	Internal, Basic Medical Scientist
Dr. Jacob John	MBBS, MD, MPH	Professor, Community Medicine, CMC, Vellore	Internal, Clinician
Dr. Ashish Goel	MBBS, MD, DM	Professor, Hepatology, CMC, Vellore	Internal, Clinician
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL.	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Dr. Prasanna Samuel	MSc, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Abhay Gahukamble	MS, D Ortho, DNB(Ortho)	Associate Professor, Paediatric Orthopaedics, CMC, Vellore	Internal, Clinician
Dr. Suceena Alexander	MBBS, MD, DM	Associate Professor, Nephrology, CMC, Vellore	Internal, Clinician
Dr. Shirley David	MSc, PhD	Professor, Head of Fundamentals Nursing Department, College of Nursing, CMC, Vellore	Internal, Nurse
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Effect of early supervised rehabilitation on Musculo Skeletal Tumor Society Rating Score (MSTS) and knee range of motion (ROM) in subjects with endoprosthetic reconstruction of proximal tibia (EPRPT)" – Experimental study" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 50,000/- INR (Rupees Fifty Thousand Only) will be granted for 1 year.

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board.

Dr. BIJU GEORGE
MBBS, MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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